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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,364	06/21/2003	Iris Ginron Zhao		7109

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Iris Zhao
#202
1028 North Lake Ave
Pasadena, CA 91104

EXAMINER	
EPPS FORD, JANET L	
ART UNIT	PAPER NUMBER
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/600,364	ZHAO, IRIS GINRON	
	Examiner	Art Unit	
	Janet L. Epps-Ford	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Applicant's election without traverse of the following in the reply filed on 2-07-07 is acknowledged. However, it is noted that the examiner withdrew the restriction requirement, and all claims were searched together.

2. Claims 1-16 are presently pending for examination.

Specification

3. The disclosure is objected to because of the following informalities: Page 1 of the specification as filed, line 19, must be amended to accurately reflect the correct US Patent number issued from application number 09/589,248. The correct US Patent number is 6,824,549. Appropriate correction is required.

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

This application is claiming the benefit of prior-filed nonprovisional application No. 09/240,832 under 35 U.S.C. 120, 121, or 365(c).

The later-filed application must be an application for a patent for an invention, which is also disclosed, in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the

requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/240,832, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. In the instant case, the claims are directed to an artificial graft for sealing and holding a body fluid within a living mammal, however the disclosure of application 09/240,832 (issued US Patent 6,171,635), is drawn to a coffee-type beverage, there is no support for the invention of the present application in the disclosure of the prior application.

Therefore, Applicants are only afforded the benefit of earlier filed application 09/589,248, which is August 07, 2000.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-2 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Nunez et al. (WO 96/17633).

7. Claims 1-2 and 6-8 are drawn to an artificial graft for sealing and holding a body fluid within a living mammal comprising an adhesive nonpyogenic fluid suitable to form a solid surrounding and sealing a body fluid. This claim is interpreted as reading on any artificial graft comprising an adhesive nonpyogenic fluid, the language "for sealing and

holding a body fluid within a living mammal" is considered an intended use limitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See MPEP § 2111.02 [R-3].II.

8. Nunez et al. discloses unsupplemented and supplemented Tissue Sealants (TS), such as fibrin glue (FG), wherein said TSs are supplemented with one or more of the following: growth factors, inhibiting compounds and/or potentiating compounds, drugs and demineralized bone (see Abstract and Background on page 1). TSs contain blood clotting factors and other blood proteins. FG, also called fibrin sealant, is a gel similar to a natural clot, which is prepared from plasma (see page 5, section B; claims 1-2, and 6-7 are anticipated by this description of Nunez et al.).

Nunez et al. describe compositions of collagen and/or fibrinogen dispersed in an aqueous medium such as an amorphous flowable mass, and a proteinaceious matrix composition (see page 11, lines 25-26).

According to Nunez et al. the compositions of their invention, have several advantages, including wherein animal cells can migrate into and through the TSs of their invention, which aids engraftment of the cells to neighboring tissues and prostheses; because of its initial liquid nature, the TS (or tissue sealant) can cover surfaces more thoroughly and completely than previously available delivery systems; additionally the tissue sealants of Nunez et al. allow for site-directed angiogenesis to occur in vivo; furthermore the tissue sealants of Nunez et al. can be molded into almost

any shape (see pages 22-25; this portion of Nunez et al. is interpreted to read on claim 8 to the extent that the tissue sealant compositions of this reference function in site-directed angiogenesis, therefore the compositions comprise an angiogenesis factor as recited in claim 8).

9. Claims 1-4, and 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Lim et al. (US Patent NO. 3,774,615).

Lim et al. discloses a device for connecting the ends of interrupted tubular organs, comprising a connecting ring over which the ends of the interrupted organs are pulled. The ring and fastening means are preferably a hydrophilic gel, which may be swollen to equilibrium or which may be an incompletely swollen hydrogel, which is subjected to additional, swelling at the place of application.

Lim et al. specifically recites the following: "[T]ests and experiments have been carried out with gels made from polymers of ethylene glycolmonomethacrylate which were cross-linked with less than 10 percent of a cross-linking agent, such as, for example, ethylene glycoldimethacrylate, or their copolymers, such as, for example, diethylene glycolmethacrylate with methylmethacrylate, acrylonitrile, methacrylic acid, and the like. However it is also possible to use other physiologically inert hydrogels, for example polymeric N-alkyl methacrylamides, N-alkyl acrylamides, N,N-dialkyl acrylamides, and the like. These hydrogels may also contain suitable drugs which facilitate healing, such as, for example, antibiotics, ***collagen***, globulin, and the like which may be introduced into the polymer before and during polymerisation or even added after polymerization when the gel is in the swollen state." (see col. 6, lines 8-24).

10. Claims 1-5, 7-9, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Bombard et al. (US Patent Application Publication No. US 2001/0007069 A1, priority to July 28, 1999).

11. Bombard et al. discloses methods of performing an anastomosis between a target vessel and the end of a graft vessel comprising the application of a tissue adhesive to the mating surfaces of the graft vessel and/or target vessel, and puncturing the adhesive comprising the use of a removable device, see paragraph [0017] of the disclosure of this publication:

> [0017] In accordance with another aspect of the present invention, a method of performing an anastomosis between a target vessel and the end of a graft vessel is provided. The method includes steps of: applying a tissue adhesive to mating surfaces of the graft vessel and/or target vessel; inserting an elongated anvil through the wall of the target vessel and positioning the anvil along an interior of the target vessel wall; positioning the end of the graft vessel adjacent an exterior of the target vessel wall; and curing the adhesive.

The adhesives useful in the methods of Bombard et al. may comprise materials such as fibrin and collagen and may be applied as a liquid or solid (see paragraph [0073] of Bombard et al.):

> [0073] In the case of adhesive bonding, the adhesive can be applied to the tissue mating surfaces of the graft and/or target vessels before the surfaces are brought into contact. The adhesive may be applied to either or both of the mating surfaces of the graft and target vessels. The adhesive may be a one part or a two part adhesive. Further, the curing of the adhesive may be activated by light or heat energy. The adhesive may be applied as a liquid or as a solid film. Preferred adhesive materials include collagen, albumin, fibrin, hydrogel and glutaraldehyde. Other adhesives such as cyano-acrylates may also be used.

12. Claims 1-4, and 6-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Murray et al. (US 2002/0123805).

13. Murray et al. discloses tissue adhesive compositions comprising collagen, an extracellular matrix protein, and a platelet. The invention further provides a composition of collagen, a platelet and a neutralizing agent, e.g. sodium hydroxide or hydrochloric acid. The method further comprises contacting the ends of an injured tissue from a patient with the compositions of this invention. The compositions can additionally include plasma, wherein the plasma is derived from the patient it is administered to, in other aspects the plasma is derived from a donor that is allogeneic to the patient (reads on claim 6). The compositions may include one or more additives, such as the following:

> **[0010]** Alternatively, the composition includes one or more additives, such as insoluble collagen, a growth factor, a cross-linking agent, a stem cell, a genetically altered fibroblast and a cell media supplement. Growth factor include for example, platelet derived growth factor-AA (PDGP-AA), platelet derived growth factor-BB (PDGF-BB), platelet derived growth factor-AB (PDGF-AB), transforming growth factor beta (TGF-β), epidermal growth factor (EGF), acidic fibroblast growth factor (aFGF), basic fibroblast growth factor (bFGF), insulin-like growth factor-1 (IGF-1), interleukin-1-alpha (IL-1α), and insulin.
>
> **[0011]** By cross-linking agent is meant that the agent is capable of forming chemical binds between the constituents of the composition. The cross-linking agent can be example, a protein or a small molecule, e.g., glutaraldehyde or alcohol.
>
> **[0012]** Cell media supplement is meant to include for example glucose, ascorbic acid, antibiotics, or glutamine.

(This passage reads on claim 7 to the extent that it discloses an adhesive composition comprising collagen, and a stem cell; this passage reads on claim 8 to the extent that the compositions of Murray et al. may comprise TGF-beta, FGF, PDGF, and/or glucose).

Claim Rejections - 35 USC § 112

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 2, 4-5, 8-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 4-5, 10 and 15-16 recite the term "solidable," the metes and bounds of this term are vague and indefinite, since the meaning of this term is uncertain. It is possible that Applicants intended the term to recite "solidifiable."

Claim 2, recites the phrase "*said* two tubular organs respectively," this phrase is vague and indefinite since there is no antecedent basis for this limitation in the claim. The term "said" in the above phrase suggests that there is an antecedent relationship. However, there is no prior recitation of the phrase "two tubular organs" in this claim.

16. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required

feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 8 recites the broad recitation hyaluronate, and the claim also recites healon (a form of hyaluronate), which is the narrower statement of the range/limitation. Additionally, claim 8 recites the broad recitation "angiogenesis factor," and also the terms "angiogenin" and "angiogenic herb extract," which are narrower statements of an "angiogenesis factor."

Additionally, claim 8, line 6, recites "arginine, alanine, arginine..," the term arginine is repeated. Appropriate correction is required.

Claim 9 recites "[T]he artificial graft system according to claim 1," there is insufficient antecedent basis for this limitation in claim 1, since claim 1 is only drawn to "an artificial graft," not to an "artificial graft system." It is suggested that Applicant amend claim 9 to recite "An artificial graft system comprising the artificial graft of claim 1, further comprising a removable device..."

It appears that claims 10-13 are drawn to the removable device of claim 9. However, claim 9 is drawn to an artificial graft system. Therefore, the nature of the invention recited in claims 10-13 is vague and indefinite, since it is unclear if the claims are only drawn to the removable device, or to the artificial graft system of claim 9, further comprising a removable device, wherein the removable device is defined as set forth in claims 10-13.

Claims 14-16 recite the phrase "*[T]he* method of making an artificial graft of claim 1." There is insufficient antecedent basis for this limitation in these claims, since claim 1

does not recite a method of making. If Applicant intended claims 14-16 to be drawn to a method for making the artificial graft of claim 1, it is recommended that Applicants amend the preamble of these claims to recite the following:

"A method for making the artificial graft of claim 1....."

Information Disclosure Statement

17. Applicant's Information Disclosure Statement (IDS) filed 6/21/03 is in improper form, Applicant's have included initials of unknown individuals in the position wherein the instant examiner was to initial the submitted IDS. Appropriate correction is requested. However, the examiner will initial near each cited document as a matter of completeness.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Janet L. Epps-Ford, Ph.D.
Primary Examiner
Art Unit 1633

JLE